

REMARKS

Claims 1-24 and 44-49 are pending; claims 25-43 stand withdrawn. No new matter has been added.

IDS

Applicants apologize for the error in the information disclosure statement filed March 30, 2009. Copies of WO 01/54813 and WO 95/33846 are included with an information disclosure statement and Form 1449 filed with this reply. Applicants ask that the Examiner please consider the references and indicate so by initialing the Form 1449.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-24 and 44-49 have been rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. The Examiner argues that the amendments filed March 30, 2009, introduced new matter to the claims as follows:

- Claims 1 and 44 and the claims that depend from them: "the volume of the chamber space being coextensive with the volume of the enclosed recess."
- Claim 47 and the claims that depend from it: "displacement distance"; "continuous wall"; "first thickness"; and "second thickness".
- Claim 49: "no fluid transfer into or out of the reaction volume is possible except when the second thickness is punctured by the cannula."

Office Action at 2-3. Applicants respectfully disagree.

According to MPEP 2163 III A, a rejection for lack of written description requires more than what the Examiner has presented in the Office Action. Specifically, MPEP 2163 III A states:

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.

Wertheim, 541 F.2d at 263, 191 USPQ at 97. In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

(A) Identify the claim limitation at issue; and

(B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description.

When appropriate, suggest amendments to the claims which can be supported by the application's written description, being mindful of the prohibition against the addition of new matter in the claims or description. See *Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326.

Here the rejection consists of a list of claim limitations objected to, and a bare conclusory statement that a person skilled in the art would not have recognized that the inventor was in possession of the claimed subject matter at the time the application was filed. The Examiner has presented neither evidence nor reasoning as to why the identified subject matter is not properly described in the specification. The rejection, therefore, has not met "the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." This alone is sufficient reason to reconsider and withdraw the rejection.

Nevertheless, in order to expedite prosecution, Applicants explain in detail how the specification provides a written description of the claim limitations identified by the Examiner.

With regard to the written description requirement, the MPEP provides

... the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such **descriptive means as words, structures, figures, diagrams, and formulas that fully set**

forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" **such as by the disclosure of drawings** or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. The subject matter of the claim **need not be described literally** (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.

MPEP 2163.02 (citations omitted) (emphasis added).

With the above in mind, support for the phrase "the volume of the chamber space being coextensive with the volume of the enclosed recess" may be found, for example, at 12-13, 30-31, and at Fig. 2. In conjunction with the reference number legend at pages 30-31 of the specification, Fig. 2 illustrates a base element 400, lid element 200, and a sealing, elastic, repeatedly puncturable intermediate element 300. Recess 301 is enclosed in intermediate element 300 and defines a reaction space. Paragraph 0047, at pages 12-13, also explains that "intermediate element 300 is characterized in that it has an enclosed recess 301. Due to this recess 301 . . . defines the volume of the reaction space (provided by 301) . . . both the geometry and the volume of the reaction space may be varied." (emphasis added). The figure and the description considered together illustrate (i.e., provide a written description of) a device in which the volume of a chamber space is coextensive with the volume of an enclosed recess.

With regard to the terms "displacement distance", "continuous wall", "first thickness", and "second thickness", reference again may be made to Fig. 2, the legend at 30-31, and the text of the specification, e.g., at 13. The illustration of sealing intermediate in Fig. 2 visually depicts a continuous wall (300) having a first thickness between first and second sealing surfaces (between 200 and 400), the first thickness defining a displacement distance between the top element and the bottom element, and a second thickness, perpendicular to the first thickness, the second thickness defining (i) lateral external dimensions of the sealing intermediate element and (ii) a predetermined interior shape of, and interior dimensions of, the reaction volume (301). Drawings

alone can be sufficient disclosure to satisfy the written description requirement. See *Vas-Cath v. Marhukar*, 935 F.2d 1555, 1565, 19 USPQ2d 1111, 1118, and MPEP 2163 II.A.3.

That "no fluid transfer into or out of the reaction volume is possible except when the second thickness is punctured by the cannula" is described, for example, at page 12: "the intermediate element is elastic and repeatedly puncturable with cannulae, wherein the cannulae are extractable and after the extraction of the cannulae a leakage of liquid from the intermediate element does not occur." (emphasis added). See the specification also at 14 and 16 ("[b]y pressing the two holding elements together, the core unit consisting of the base, intermediate and lid element is sealingly compressed.") (emphasis added).

Applicants respectfully ask that the rejection under 112, first paragraph be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 1-24 and 44-49 have been rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Application Publication No. 2006/0160205 to Blackburn et al. ("Blackburn") in view of U.S. Patent Application Publication No. 2002/0150933 by Ehricht et al. ("Ehricht"), U.S. Patent No. 5,856,174 to Lipshutz et al. ("Lipshutz"), and U.S. Patent Application Publication No. 2003/0091477 to Paul et al. ("Paul"). Office Action at 3-11. Applicants respectfully disagree. Claims 1, 44, and 47 are independent.

Claim 1 relates to a device for holding a substance library carrier. The device includes two holding elements that are fixable with each other, and that hold a layer composite that includes: (i) a solid lid element having a detection surface with a substance library on its underneath side and being optically translucent at least in an area of the detection surface, (ii) a sealing intermediate element having an enclosed recess; and (iii) a solid base element being optically translucent at least in an area of the detection surface of the lid element. The lid element, the intermediate element and the base element are held together between the two fixed holding elements to form a closed optically translucent chamber having a chamber space. The volume of the chamber space is coextensive with the volume of the enclosed recess. See claim 1.

Claim 44 relates to a first device for filling a second device for holding a substance library carrier. The second device includes two holding elements that are fixable with each other, and that hold a layer composite as described above. See claim 44.

Claim 49 relates to a device for holding a substance library carrier, comprising two holding elements that are fixable with each other and that hold a replaceable layer composite defining a reaction volume. The layer composite includes a solid top element having an optically translucent region with an array immobilized on a reaction-volume-facing surface of the optically translucent region, a solid bottom element opposed to the top element, and having an optically translucent region, and a sealing intermediate element. The sealing intermediate element includes a first sealing surface arranged to form a liquid-tight seal when pressed against the reaction-volume-facing surface of the top element, a second sealing surface arranged to form a liquid-tight seal when pressed against a reaction-volume-facing surface of the bottom element, and a continuous wall; the continuous wall has a first thickness between the first and second sealing surfaces, the first thickness defining a displacement distance between the top element and the bottom element, and a second thickness, perpendicular to the first thickness, the second thickness defining (i) lateral external dimensions of the sealing intermediate element and (ii) a predetermined interior shape of, and interior dimensions of, the reaction volume.

Applicants respectfully disagree that the claims are obvious over the cited references. To briefly summarize the discussion below, the references (whether considered alone or in combination) do not teach all of the limitations, and there is no motivation to combine features of the references to arrive at a device described in the claims.

Blackburn

Blackburn relates generally to biochip multiplexing (abstract). Cartridges are described in which a biochip substrate serves as one "half" of a reaction chamber, and a housing as the other "half." Blackburn at 0132. A separate sealing mechanism is not required for such cartridges. *Id.*

The Examiner argues that Blackburn further teaches, at paragraph 0088, that the reaction chamber has "inlet ports comprising a seal, and wherein the seal comprises a gasket, reading on a sealing intermediate." Office Action at 5.

Applicants traverse the contention that the "gasket" referred to at paragraph 0088 reads on the sealing intermediate of the instant claims. The relevant portion of Blackburn explains that an "inlet port may optionally comprise a seal . . . (as depicted in FIG. 3C and 14B) the seal comprises a gasket, or valve through which a pipette or syringe can be pushed." (emphasis added). Blackburn does not describe a structural relationship among the gasket, a lid element, and a base element--there is no indication that the gasket is intermediate a lid element and a base element.

The Examiner argues that a gasket provides "a 'recess' and the volume in the 'recess' can provide an open volume or can be filled (e.g. similar to an o-ring)." Office Action at 4. However, Blackburn does not describe a device in which the volume of the chamber space is coextensive with the volume of the enclosed recess. Even if the gasket of Blackburn is considered to have an enclosed recess (which Applicants do not concede), the gasket is taught as being part of a seal on an inlet port. The volume of the reaction chamber is defined primarily by the biochip substrate and the cartridge housing (see, e.g. FIGS. 3C and 14B of Blackburn).

Applicants agree with the Examiner's conclusion that Blackburn does not teach holding elements that hold a layer composite having a lid element, intermediate element, and base element.

Ehricht

The Examiner argues that Ehricht "discloses two holding elements that are fixable with each other (for example, see figure 1 [sic, figure 2] wherein the 'two sides' of element 42 represent 'holding elements' and they are 'fixed' at a distance equal to the length of element 2.)" See the Office Action at page 7. Applicants respectfully disagree.

The Examiner misinterprets figures 1-2 of Ehricht. Ehricht does not disclose "two holding elements that are fixable with each other" as the Examiner asserts, but instead a **single**

chamber body (element 1). See, e.g., paragraph 0055: "Device 20 . . . consists of a chamber body 1" Figures 1 and 2 of Ehricht are reproduced below for reference.

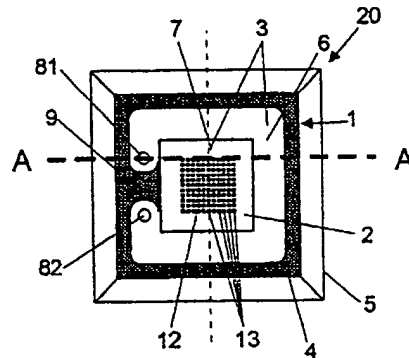


Fig. 1

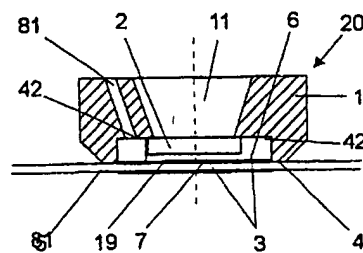


Fig. 2

Thus, Ehricht does not teach **two** holding elements that are fixable with each other.

According to the Examiner, Ehricht does teach such an element, specifically "a chamber body and chamber support wherein the chamber body is provided with a bearing surface via which chamber body is in a sealing connection with chamber support, so that a sample chamber is formed." Office Action at 7. Applicants respectfully disagree that the description of a chamber body "in a sealing connection" with a chamber support can reasonably be interpreted as teaching a sealing intermediate element having an enclosed recess.

Ehricht describes a device having two elements (i.e., a chamber body and a chamber support) in a sealing connection with one another. There is no third, intermediate element. Rather, the sealing connection is "by means of an adhesive connection or weld connection" (Ehricht at 4, paragraph 0055).

The present claims, however, recite a device having **three** elements: (i) a lid element; (ii) a sealing intermediate element; and (iii) a base element. For example, compare FIGS. 2 and 5 of Ehricht (showing chamber body 1 and chamber support 5) with FIG. 2 of the present application

(showing lid element 200, sealing intermediate element 300, and base element 400, as well as holding elements 101 and 102; see the specification, e.g., at 6, paragraph 0029). The specification describes that in one embodiment, the device includes a "layered reaction chamber 500 consisting of the base element 400, the intermediate element 300, and the lid element 200 . . . mounted in the holding elements 101 and 102 that may be engaged with one another." Specification at 15, paragraph 0058.

Applicants' arguments regarding the teachings of Ehricht have not been addressed.

Lipshutz

The Examiner argues that Lipshutz "teaches in **column 19, lines 20-29** . . . use of an oligonucleotide array (substance library carrier as the bottom surface of a chamber," and "[i]n **column 27, lines 1-3** . . . that the base unit [may] include a second surface which contacts the opposite surface of the device." (emphasis added) (Office Action at 11-12). It is not clear that Lipshutz is describing a single device in these passages selected from disparate portions of the disclosure. Nevertheless, neither the passages mentioned above, nor any other part of Lipshutz, describes a device including two holding elements that are fixable with each other, and that form a layer composite that includes **a sealing intermediate element having an enclosed recess**.

The Examiner argues that a gasket (Lipshutz refers to a sealable closure or septum, col. 18, lines 5-19) provides "a 'recess' and the volume in the 'recess' can provide an open volume or can be filled (e.g. similar to an o-ring)." Advisory Action at 2. However, Lipshutz does not describe a device in which the volume of the chamber space is coextensive with the volume of the enclosed recess. Even if the septum of Lipshutz is considered to have an enclosed recess (which Applicants do not concede), the septum is taught as being part of a sealable closure on a opening to the outside of the device (i.e., an inlet). The volume of the reaction chamber is defined primarily by the molded or machined wells of a polymeric part (Lipshutz at col. 15, line 48 to col. 16, line 2).

Lipshutz indicates that the body of the device "may be embodied in any number of shapes" (Lipshutz at column 14, lines 15-17). With regard to claim 9, the broad, unspecific

teaching of Lipshutz does not teach, suggest, or provide motivation for a person of ordinary skill in the art to make a chamber space in the shape of a D, a new moon, or a sickle.

Paul

Paul describes a system for hybridization assays that includes a cartridge for housing an array device. The Examiner, with reference to Fig. 3 of Paul, argues that "at least elements 350 and 310 serve as fixed holding elements."

Paul relates to a chip holder and a cartridge for the chip holder, which are particularly adapted for a flow-thru chip (FTC) (Paul at paragraphs 0011-0016).

Paul does not describe a device having a solid lid element, a sealing intermediate, and a solid base element, where the lid element, the intermediate element and the base element are held together between two fixed holding elements to form a closed chamber having a chamber space. In contrast, the nature of an FTC requires a fluid inlet and outlet so as to permit flow through the chip. In other words, the chamber in the device discussed by Paul is necessarily not a closed chamber.

The Examiner has not directly addressed the content of Paul with regard to a sealing intermediate element. Nevertheless, Paul explains that

... upper seal(s) 333, 334, [] can be a single seal, as shown in FIG. 6B. The single upper seal 335 further includes a hole 336 and a slot or channel 337. The location of hole 336 corresponds to the location of the exit hole 429 (FIG. 4D), which directs test (or process) fluid that has passed through the FTC to the exit guide hole 409 and out of the FTC cartridge.

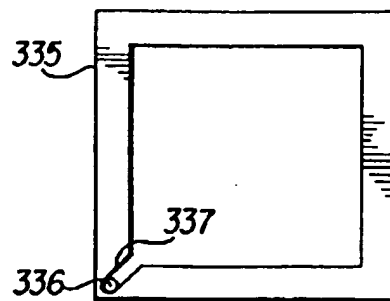


FIG. 6B

Paul at paragraphs 0083-0084 and FIG. 6B. The above passage and figure clearly contemplate a flow through device. The slot, channel and exit hole are inconsistent with a sealing intermediate element having an **enclosed** recess. Paul's flow through device, rather than enclosing a fluid, permits flow.

Because the chip holder is used with an FTC, it includes a port for passing test fluid into the test fluid chamber. The holding device of Paul is intended for use with a FTC, where the array is immobilized inside the channels of the FTC. Nowhere does Paul teach, suggest, or motivate using the holding device with a "flat surface" array. Paul contrasts FTC devices with "flat surface" substrates (*Id.* at paragraph 0003). According to Paul, other FTC holders are associated with difficulties such as leaking and insufficient flow control (paragraphs 0007-0008). Paul then explains why "conventional gene chip array holders (or cartridges). . . operate[] with a non-flow-through substrate. . . . Therefore, this type of conventional design is inadequate to address fluid flow and leakage issues." *Id.* at paragraphs 0009-0010. Paul thus actively discourages the combination the FTC devices with non-flow-through devices. Blackburn, Ehricht, and Lipshutz are all concerned with devices that operate with a non-flow-through substrate. Thus, Paul teaches away from combination with the teachings of Blackburn, Ehricht, and Lipshutz. Combining references is improper where the references teach away from their combination. See, e.g., MPEP 2145 X.D and 2141.02. For at least this reason, the instant claims are nonobvious over Blackburn, Ehricht, Lipshutz and Paul. Applicants therefore respectfully ask that the Examiner reconsider and withdraw the rejection.

Combination of the references

Nothing in the references provides a teaching, suggestion, or motivation to supply the missing elements, nor does common sense or skill in the art supply what the references lack. Here, the references, when considered together, do not teach, suggest, or motivate a person having ordinary skill in the art to make a device including two holding elements that are fixable with each other, and that hold a layer composite which includes a solid lid element, a sealing intermediate element having an enclosed recess, and a solid base element; where the lid element, the intermediate element and the base element are held together between the two fixed holding

elements to form a closed optically translucent chamber having a chamber space, the volume of the chamber space being coextensive with the volume of the enclosed recess.

Even if the art of record taught all of the features detailed in claim 1 (which Applicants do not concede), there is no motivation to combine those features to arrive at the claimed device. For example, Ehricht does not teach a sealing intermediate element. Blackburn and Lipshutz teach a gasket and a septum, respectively, as seals for inlet ports. Even if the gasket and/or septum are considered to have an enclosed recess, neither Blackburn nor Lipshutz teaches or suggests a configuration where the volume of a closed chamber space is coextensive with the volume of the enclosed recess. Paul teaches a device that includes a sealing element positioned between a flow through cell and a window. It does not teach a closed chamber space; nor a closed chamber space that has a volume coextensive with the volume of the enclosed recess; nor that a lid, an intermediate element and a base element are held together to form a closed chamber. Even if the references teach the parts that appear in claim 1, there is no teaching, suggestion, or motivation to combine those parts in the manner (e.g., the structural relationships among the parts) described in claim 1.

Furthermore, Paul explicitly teaches away from devices like those discussed in Blackburn, Ehricht, and Paul, and therefore may not be properly combined with those references.

The Supreme Court has explained that to facilitate review of a determination of obviousness, the analysis of "interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art. . . should be made explicit." *KSR International Co. v. Teleflex Inc.* 550 U.S. 398 (2007) (citing *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")).

Here, the Examiner has failed to provide any reasoning behind the combination of Blackburn, Ehricht, Lipshutz and Paul. For, example, there is no explanation of how the teachings of the references are "interrelated," only a list of features allegedly taught by each

reference. There is no reason to combine the various teachings in a way that would lead a person of ordinary skill to the devices of claims 1, 44, 47 or the claims that depend from them.

The amendments and new claims presented in the paper filed on March 30, 2009, have not been addressed.


In short, the Examiner has failed to make a *prima facie* case of obviousness. Applicants therefore respectfully ask that the rejection under § 103 be reconsidered and withdrawn.

CONCLUSION

Applicants ask that all claims be allowed. Please apply any other charges or credits to deposit account 19-4293.

Respectfully submitted,

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